6 February 2023

ImmuPharma PLC
("ImmuPharma" or the "Company")

Lupuzor™ Update
Phase 2/3 adaptive study design for Lupus study agreed with Avion

ImmuPharma PLC (LSE:IMM), the specialist drug discovery and development company, provides an update to the market on its Lupuzor™ programme in patients with systemic lupus erythematosus ("SLE")

Key highlights:

- In conjunction with its partner Avion Pharmaceuticals ("Avion"), ImmuPharma confirms that a Phase 2/3 adaptive trial will be the best design for the next clinical study of Lupuzor™ in SLE patients
- The study is targeted to commence in H2 2023 following submission through the FDA/PDUFA* process

ImmuPharma confirms that with its partner Avion, they have agreed on an adaptive Phase 2/3 study for Lupuzor™ in SLE patients. This is a one-protocol pivotal study which allows exploration of a dose-range in the Phase 2 part of the study, followed by seamless progression into the Phase 3 part of the study at the chosen dose. The overall timelines for the lupus clinical program are shorter as one avoids the need for stopping and starting two independent trials, regulatory checks, ethics approvals and site set-ups. It is also expected to be less costly overall. There is also an opportunity, through an interim analysis in the Phase 3 part of the study, to stop the study earlier if an efficacy signal is reached after a certain percentage of patients have been treated.

This new study design incorporates guidance from the Food and Drug Administration ("FDA") which advised exploration of higher dose levels than have been used in the clinical program to date. A clean safety profile has already been established at higher doses. The ImmuPharma/Avion team, together with external advisors, are now preparing an updated clinical protocol.

Commenting on the announcement, Tim McCarthy, CEO of ImmuPharma, said:

"We have had extremely productive discussions with Avion over the last few weeks on the Lupuzor™ programme and we have agreed that the optimum way forward for Lupuzor™ is to undertake an adaptive Phase 2/3 trial. Our key focus will be to commence the trial during H2 2023."

This announcement contains inside information as stipulated under the UK version of the Market Abuse Regulation no 596/2014 which is part of English law by virtue of the European (withdrawal) Act 2018, as amended. On publication of this announcement via a regulatory information service, this information is considered to be in the public domain.

Ends

*FDA | Food and Drug Administration

* PDUFA | Prescription Drug User Fee Act

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Notes to Editors

About ImmuPharma PLC

ImmuPharma PLC (LSE AIM: IMM) is a specialty biopharmaceutical company that discovers and develops peptide-based therapeutics. The Company's portfolio includes novel peptide therapeutics for autoimmune diseases and anti-infectives. The lead program, P140 (Lupuzor™), is a first-in class autophagy immunomodulator for the treatment of Lupus and preclinical analysis suggest therapeutic activity for many other autoimmune diseases that share the same autophagy mechanism of action.

For additional information about ImmuPharma please visit www.immupharma.co.uk

About Avion Pharmaceuticals LLC

Avion Pharmaceuticals, LLC, is a specialty pharmaceutical company formed to develop, acquire and market a portfolio of innovative pharmaceutical products in the Women's Health and other therapeutic categories aligned with its mission to improve the quality of patient lives. Avion Pharmaceuticals focuses on identifying opportunities to develop, acquire and enhance the market potential of innovative, commercially available therapeutics and late-stage development drugs to fulfil unmet medical needs.

For more information, visit www.avionrx.com.

About Lupus (Systemic Lupus Erythematosus / SLE)

Lupus is a chronic inflammatory disease which is thought to affect some 5 million individuals worldwide. The current standard of care still consists of steroid and anti-malarial therapies which many have side-effects and poor response in many patients. Recently more targeted monoclonal therapies are GlaxoSmithKline's Benlysta and more recently, AstraZeneca's Saphnelo. There still exists a high unmet medical need for a drug that has a strong efficacy and safety profile.

About PDUFA

The Prescription Drug User Fee Act (PDUFA) was a law passed by the United States Congress in 1992 which allowed the Food and Drug Administration (FDA) to collect fees from drug manufacturers to fund the new drug approval process. The Act provided that the FDA was entitled to collect a substantial application fee from drug manufacturers at the time a New Drug Application(NDA) or Biologics License Application (BLA) was submitted, with those funds designated for use only in Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) drug approval activities. In order to continue collecting such fees, the FDA is required to meet certain performance benchmarks, primarily related to the speed of certain activities within the NDA review process.

ImmuPharma's LEI (Legal Entity Identifier) code : 213800VZKGHXC7VUS895.